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| 10/569,958 | 11/03/2006 | Kristine Fuimaono | 32860-001018/US | 3084 |
| 30596 | 7590 | 08/09/2010 | EXAMINER | |
| HARNESS, DICKEY & PIERCE, P.L.C. | | | NGUYEN, HIEN NGOC | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/569,958 | FUIMAONO ET AL. |
| | Examiner | Art Unit |
| | Hien Nguyen | 3768 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 11 June 2010.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-26 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-26 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 28 February 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>03/29/2010</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

This action is responsive to the Arguments/Amendments filed 06/11/2010.

Amendments to claims 1, 12-13, 19, 22 and 25-26 have been entered. Claims 1-26 are now pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-3, 5, 8-9, 12, 14 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695) and in view of Rose (US 2002/0176608).

3. Addressing claim 12, Packer discloses a device comprising: at least one input interface for electroanatomical 3D mapping data and 3D image data (see Fig. 1, col. 2, lines 14-60, col. 3, lines 51-67, Packer discloses a device that perform an imaging method therefore the device must have at least one input interface for electroanatomical 3D mapping data and 3D image data); a segmentation module that is capable of

segmenting the 3D image data in order to extract a 3D surface profile of objects contained within a volume record by way of the 3D image data (see Fig. 2A, col. 6, lines 14-45 and col.7, lines 7-23); a registration module connected to the segmentation module constructed configured to automatically correlate with the correct position and dimension of the electroanatomical 3D mapping data and the 3D image data representing the 3D surface image, by surface matching of the 3D surface profile from the 3D image data to a 3D surface image from the 3D mapping data in at least one stage of the registration (see Fig. 1, Fig. 8, col. 2, lines 14-60 and col. 9, line 21-col.10, line 36) and a visualization module connected to the registration module superimpose the 3D mapping data and at least the 3D image data representing the 3D surface images on one another in the correct position with the correct dimension and provide these for visualization via a display device (see Fig. 1, Fig. 8, col. 2, lines 14-60 and col. 9, line 21-col.10, line 36; when superimpose one image on another it would have been obvious to one of ordinary skill in the art to co-register the images in order to have accurate match between the images). However, Packer does not explicitly disclose surface profile. Rose discloses surface profile provide images of the surface with fine detail (see claim 9 and [0005-0007]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer to include surface profile as taught by Rose because the surface profile provide extensive detail about the surface.

4. Addressing claim 14, Packer discloses visualization module that is capable of real time visualization of a part of a catheter that is used within a representation of the

3D image data that forms at least the 3D surface images (see col. 2, line 14-60 and col. 13, lines 1-23). Rose discloses surface profile (see claim 9 and [0005-0007]).

5. Addressing claim 1, Packer discloses a method for visually supporting an electrophysiology catheter application in the heart, comprising: visualizing electroanatomical 3D mapping data, provided during the performance of the catheter application, of an area of the heart to be treated (see Fig. 1, col. 2, lines 14-60, col. 11, lines 33-48 and col. 12, lines 28-61); recording 3D image data of the area to be treated with a method of tomographical 3D imaging before the catheter application is carried out (see col. 2, lines 25-37); extracting a 3D surface images of objects in the area to be treated from the 3D image data by segmentation (see col. 5, line 63-col.6, line 48); the visualized electroanatomical 3D mapping data and 3D image data representing at least the 3D surface image being registered, with correct position and dimension, by automatically correlating the electroanatomical 3D mapping data and 3D image data representing the 3D surface image by surface matching, in at least one stage of registration, the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data (see Fig. 1, Fig. 8, col. 2, lines 14-60 and col. 9, line 21-col.10, line 36; when superimpose one image on another it would have been obvious to one of ordinary skill in the art to co-register the images in order to have accurate match between the images). However, Packer does not explicitly disclose surface profile. Rose discloses surface profile provide images of the surface with fine detail (see claim 9 and [0005-0007]). It would have been obvious to one of ordinary skill in the art at the time of

the invention to modify Packet to include surface profile as taught by Rose because the surface profile provide extensive detail about the surface.

6. Addressing claims 19 and 22, a method and device for visually supporting an electrophysiology catheter application in the heart, comprising: recording 3D image data of an area of the heart to be treated with a method of tomographical 3D imaging, before electroanatomical 3D mapping data is provided during the performance of the catheter application (see col. 2, lines 25-37); extracting a 3D surface images of objects in the area to be treated from the 3D image data by segmentation (see col. 5, line 63-col.6, line 48); registering, with correct position and dimension, by automatically correlating the electroanatomical 3D mapping data and 3D image data representing the 3D surface profile by surface matching, in at least one stage of registration, the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data (see Fig. 1, Fig. 8, col. 2, lines 14-60 and col. 9, line 21-col.10, line 36); and displaying 3D mapping data and the 3D image data representing the 3D surface profile superimposed on one another in correct dimension and position (see Fig. 1, Fig. 8, col. 2, lines 14-60 and col. 9, line 21-col.10, line 36). However, Packer does not explicitly disclose surface profile. Rose discloses surface profile provide images of the surface with fine detail (see claim 9 and [0005-0007]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packet to include surface profile as taught by Rose because the surface profile provide extensive detail about the surface.

7. Addressing claims 2-3, 5, 8-9, 20-21 and 23-24 wherein the 3D image data of the area to be treated are recorded with a method of at least one of X-ray computer tomography and magnetic resonance tomography (see col. 1, lines 15-35 and col. 3, lines 51-67); wherein the 3D image data of the area to be treated are recorded by use of a 3D ultrasound (see col. 1, lines 15-35 and col. 3, lines 51-67); the 3D image data are visualized via a volume rendering technique (see col. 6, line 1-13); wherein a registration is effected between a catheter used during the catheter application and the 3D image data and at least a part of the catheter is visualized in real time in the representation of the 3D image data representing at least the 3D surface images (see col. 2, lines 53-60, col. 3, lines 25-38 and Figs. 3-7); visualize catheter without superimposition of the 3D mapping data from time to time (see col. 2, lines 53-60).

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695), in view of Rose (US 2002/0176608) and further in view of Hemler et al. (A System for Multimodality Image Fusion (provided as prior art in the IDS)) and further in view of Williams et al. (DE 19953308-A1 (provided as prior art in the IDS)).

9. Addressing claim 4, Packer does not disclose registering with the correct position and dimension by automatically correlate using distinct anatomical points and artificial marker. Hemler discloses register by correlate the correct position and the correct dimension using distinct anatomical points as an effective way to ensure the images on display are in correct position and dimension (see page 337, line 7- page 338, line 32).

Williams discloses correlate the correct position and the correct dimension using artificial marker as an effective way to ensure the images on display are in correct position and dimension (see abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer's system to correlate the correct position and the correct dimension using distinct anatomical points and artificial marker taught by Hemler and Williams because using distinct anatomical points and artificial marker are effective way to ensure the images display are in correct position and dimension.

10. Claims 13, 18 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695), in view of Rose (US 2002/0176608), further in view of Hemler et al. (A System for Multimodality Image Fusion (provided as prior art in the IDS)) and Williams et al. (DE 19953308-A1 (provided as prior art in the IDS)).

11. Addressing claims 13 and 25-26, Packer does not disclose correlate the correct position and the correct dimension using distinct anatomical points and artificial marker. Hemler discloses correlate the correct position and the correct dimension using distinct anatomical points as an effective way to ensure the images on display are in correct position and dimension (see page 337, line 7- page 338, line 32). Williams discloses correlate the correct position and the correct dimension using artificial marker as an effective way to ensure the images on display are in correct position and dimension

(see abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer's system to correlate the correct position and the correct dimension using distinct anatomical points and artificial marker taught by Hemler and Williams because using distinct anatomical points and artificial marker are effective way to ensure the images display are in correct position and dimension.

12. Addressing claims 18, Packer discloses visualization module is constructed for visualizing a part of a catheter used within a representation of the 3D image data, forming at least the 3D surface profile, in real time (see col. 2, line 14-60).

13. Claims 10-11 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695), in view of Rose (US 2002/0176608) and further in view of Solomon et al. (US 2003/0018251).

14. Addressing claims 10-11 and 17, Packer and Rose do not disclose an instantaneous distance of a catheter tip from a predetermined picture element of the 3D image data and the distance is represented by color coding of the visualization of the catheter. Solomon discloses an instantaneous distance of a catheter tip from a predetermined picture element of the 3D image data and the distance is represented by color coding of the visualization of the catheter (see [0056-0058]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer's method to have an instantaneous distance of a catheter tip from a

predeterminable picture element of the 3D image data and the distance is represented by color coding of the visualization of the catheter as taught by Solomon because the coded representation provide a better visualization for the operator and the operator can easily determine the distance by looking at the color code.

15. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695), in view of Rose (US 2002/0176608) and further in view of Solomon et al. (US 2003/0018251).

16. Addressing claims 15-16, Packer does not disclose a calculation module to calculate an instantaneous distance of a catheter tip from a predeterminable picture element of the 3D image data. Packer also does not disclose the visualization module for the coded representation of the calculated distance in real time. Solomon discloses a system that included a calculation module to calculate an instantaneous distance of a catheter tip from a predeterminable picture element of the 3D image data, the visualization module and a method step for the coded representation of the calculated distance in real time for better visualization for the operator (see [0056-0058]). The calculated module is inside the system. The system has to have a calculation module in order to make the calculation. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer's system with a calculation module to calculate an instantaneous distance of a catheter tip from a predeterminable picture element of the 3D image data, the visualization module being constructed for the coded

representation of the calculated distance in real time taught by Solomon because the coded representation provide a better visualization for the operator and the operator can easily determine the distance by looking at the color code.

17. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695), in view of Rose (US 2002/0176608) and further in view of Massaro et al. (2002/0087329).

18. Addressing claim 6, Packer and Rose do not disclose visualized image data on a polygonal grid. Massaro discloses visualize image on a polygonal grid for easily matching location and distance (see claim 58). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer's method to visualized image data on a polygonal grid taught by Massaro because with a polygonal grid the viewer can easily match location and determine distance.

19. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Packer et al. (US 6,556,695), in view of Rose (US 2002/0176608), in view of Shoji et al. (US 6,572,476) and further in view of Chiu et al. (US 2004/0233217).

20. Addressing claim 7, Packer and Rose do not disclose adjustable transparency and adjustable blending factor. Shoji discloses adjustable transparency to make the image more or less visible (see col. 9, lines 1-22). Chiu discloses adjustable blending

factor to control the visibility of the output image (see [0007-0008]). It would have been obvious to one of ordinary skill in the art to modify Packer's method with adjustable transparency and adjustable blending factor taught by Shoji and Chiu because adjustable transparency and adjustable blending factor allow the operator to adjust the level of visibility of the images.

Response to Arguments

Applicant's arguments filed 06/11/2010 have been fully considered but they are not persuasive. Regarding claims 12 and 14, applicant argues Packer does not disclose 3D mapping data, automatic registration of the 3D image data and electroanatomical 3D mapping data. Applicant's argument is not persuasive because Packer discloses 3D mapping data (see col. 2, lines 45-49, col. 12, lines, 35-43, electrical activation map produce from the acquired electrophysiological data is the 3D mapping data) and automatic registration of the 3D image data and electroanatomical 3D mapping data (see col. 2, lines 45-49, according to applicant's specification page 4, the 3d mapping data is superimposed or register on the 3d image data; Packer discloses overlay/merge 3d mapping data on 3d high resolution image data and this is the same as superimposed perform by the applicant; the overlay is performed by computer therefore it is an automatic process; when superimpose one image on another it would have been obvious to one of ordinary skill in the art to co-register the images in order to have accurate match between the images). Applicant argues Packer does not disclose

surface profile. Applicant's argument is not persuasive because this is being addressed by Rose.

Applicant argues it would not have been obvious to one of ordinary skill in the art at the time of the invention to modify Packer with Rose because they are non-analogous art and motivation to combine is not suggested in Rose or Packer. Applicant's argument is not persuasive because Packer and Rose are in the same field of imaging and image analysis. Further, Rose's paragraph [0005] suggests using surface profile to display fine detail of the object's surface in the images therefore one of ordinary skill in the art at the time of the invention would modify Packer with Rose to display fine detail of the heart surface.

Applicant argues Packer, Hemler and William do not disclose multi-stages registration. Applicant's argument is not persuasive because Packer discloses registration module that perform surface matching, Hemler discloses registration using distinct anatomical points, William discloses registration using fiducial markers therefore Packer's device in view of Hemler and William perform all of these registration techniques and these registration techniques must be performed at different stages or different time therefore this registration process is the same as multi-stages registration. The device can not perform two registrations at the same time.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HIEN NGUYEN whose telephone number is (571)270-7031. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768